



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Print Date: 6/14/22

Title: Jasper and Newton Counties (JNC) Missouri Lead Exposure Investigation

Project Id: 0900f3eb81f160cd

Accession #: NCEH-EIT-5/5/22-160cd

Project Contact: Erin J Evans

Organization: NCEH/ATSDR/OCHHA/WS

Status: Pending Clearance

Intended Use: Project Determination

Estimated Start Date: 05/26/2022

Estimated Completion Date: 03/31/2023

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: 0923-0048

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research / Other <i>45 CFR 46.102(l)</i> Environmental Sampling Non-Epi Aids Investigations	6/14/22	Davis_Stephanie I. (sgd8) CIO HSC

PRA:
PRA Applies

6/14/22

Davis_Stephanie I. (sgd8) CIO OMB / PRA

Description & Funding

Description

Priority:	Urgent
Date Needed:	05/26/2022
Priority Justification:	The current extension ICR for #ATSDR Exposure Investigations# (OMB Control No. 0923-0048) will need to be extended until 6/30/2022 by OMB. This requires urgent approval to meet summer deadlines.
Determination Start Date:	05/05/22
Description:	The EI will measure blood lead levels (BLLs) and lead in environmental samples in and around homes near the Oronogo-Duenweg Mining Belt and Newton County Mine Tailings Superfund sites. ATSDR will compare the results with the CDC blood lead reference values of 3.5 #g/dL for children and 5 #g/dL for adults, provide participants with their individual results and interpretation/recommendations, and write a summary report (EI report). This EI will result in an increased education about preventing lead exposure, improved access to recommendations for remedial or removal actions, and to the knowledge needed to guide future remediation of lead in the area.
IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Primary Priority of the Project:	Not selected
Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	The EI will measure blood lead levels (BLLs) in 225 children (<72 months) and 75 pregnant women or women of childbearing age (15-44 years) near the Oronogo-Duenweg Mining Belt and Newton County Mine Tailings Superfund sites. EPA and MDHSS will sample lead contamination in and around households to allow a better evaluation of BLLs. ATSDR will compare the results with the CDC blood lead reference value of 3.5 #g/dL for children and 5 #g/dL for adults, provide participants with their individual results and interpretation/recommendations, and write a summary report (EI report). This EI will result in an increased education about preventing lead exposure, improved access to recommendations for remedial or removal actions, and to the knowledge needed to guide future remediation of lead in the area.

Objective:

The EI has the following objectives: 1. Evaluate BLLs in Jasper and Newton County residents, who are children (<72 months) and women who are pregnant or of childbearing age (15-44 years) that participate in the investigation. 2. Review environmental sampling data collected by state and federal partners. Samples will be taken from participating residents# indoor and outdoor environments including soil, drinking water from private wells at the tap, public water collected at the tap, household dust, and interior and exterior painted surfaces. 3. Administer a survey questionnaire to document demographic, behavioral, occupational, and educational information of participants. Parents/guardians will complete the survey for the child participants. 4. Evaluate lead levels in environmental samples and the association between environmental lead levels with BLLs. 5. Recommend ways to lower environmental exposures to lead. 6. Provide an opportunity for all participants and parents/guardians of child participants to discuss their blood lead findings with an ATSDR medical officer.

Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?: Yes

Project does not incorporate elements of health equity science: Not Selected

Measuring Disparities: Not Selected

Studying Social Determinants of Health (SDOH): Not Selected

Assessing Impact: Yes

Methods to Improve Health Equity Research and Practice: Not Selected

Other: Not Selected

Activities or Tasks: New Collection of Information, Data, or Biospecimens

Target Populations to be Included/Represented: Children ; Pregnant Women

Tags/Keywords: Lead ; Mining ; Environmental Exposure

CDC's Role: CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens

Method Categories: Convenience Sample; Exposure Investigation; Health Education; Individual Interviews (Qualitative)

Participants for the EI will be recruited from the areas within the Oronogo-Duenweg Mining Belt and Newton County Mine Tailings Superfund sites# boundaries. The EI will seek participants who reside in areas where soil lead contamination is highest or suspected to be present. ATSDR will use site investigations and historic site sampling data provided by EPA Region 7 to identify these areas. Up to 300 participants will be enrolled. Children < 72 months, pregnant women, and women of childbearing age will be eligible for inclusion. ATSDR will also evaluate BLLs for minor siblings of participants ? 72 months, if requested by a parent or guardian, as a public health service to the community. However, their results will not be evaluated as part of the EI, and they will not be compensated as a eligible participant. ATSDR will perform the following recruitment activities: 1. ATSDR will create a mailing list for the residents in Jasper and Newton Counties where lead contamination is known to be present or where environmental investigations are pending. Contact information will be provided for participants to make appointments for testing. 2. Fact sheets, fliers, and postcards providing information on testing will be prepared by ATSDR and provided to LPHAs, distributed to eligible participants, and printed in local news publications and online outlets. 3. Digital recruitment material will be developed, and targeted social media advertising will be purchased. Click and impression advertisements will be purchased through Facebook and Instagram. Advertisements will target women with children, women who are pregnant, women of childbearing age, men with

Methods:

children, and grandparents. 4. ATSDR will develop a webpage to display information about the EI, eligibility criteria, and enrollment information. 5. ATSDR will focus on daycares, preschools, and elementary schools in the area to request partnership to recruit from client families. 6. ATSDR will recruit through established or newly created in-person connections with the community. Recruitment will occur through local events or public information sessions aimed at community groups, religious organizations, or other influential community members including elected officials. 7. ATSDR will work with LPHAs and local media outlets to broadcast recruitment information via radio or local news channels. 8. ATSDR will work with MDHSS, LPHAs, and the PEHSU to provide recruitment information and material to area PCPs, pediatricians, clinicians, and other area healthcare providers. 9. A \$20 token of appreciation in the form of a cash gift card will be provided to each eligible participant. Participants will receive the gift card at the time of blood draw. 10. Recruitment efforts will stop once the participation goal of 225 children <72 months and 75 pregnant women or women of childbearing age (15-44 years) has been met. Collection: 1. There will be two blood collection events. There will be one event at a central location for each county, to reduce travel burden on participants (ATSDR). 2. Administer a questionnaire to document demographic, behavioral, occupational, and educational information of participants (ATSDR). Parent/guardians will complete the survey for child participants. 3. Environmental samples will be collected from participants' households within 90 days of blood collection (EPA and MDHSS).

Collection of Info, Data or Biospecimen:

Blood will be collected from participants as well as environmental samples from in and around the house. Additional information will be collected via questionnaire.

Expected Use of Findings/Results and their impact:

ATSDR and partners will evaluate blood lead levels and lead levels in environmental samples to determine the association between environmental lead levels and BLLs. This EI will result in an increased education about preventing lead exposure, improved access to recommendations for remedial or removal actions, and to the knowledge needed to guide future remediation of lead in the area.

Could Individuals potentially be identified based on Information Collected? Yes

Will PII be captured (including coded data)? Yes

Does CDC have access to the identifiers (including coded data)?: Yes

Is this project covered by an Assurance of Confidentiality? No

Does this activity meet the criteria for a Certificate of Confidentiality (CoC)? No

Is there a formal written agreement prohibiting the release of identifiers? No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	APPLETREE				

Other-Funded by ATSDR operating funds	Staff Time Only				0.00
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HSC Review

HSC Attributes

Environmental Sampling	Yes
Non-Epi Aids Investigations	Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office No

Estimated number of study participants

Population - Children Protocol Page #:

Population - Minors Protocol Page #:

Population - Prisoners Protocol Page #:

Population - Pregnant Women Protocol Page #:

Population - Emancipated Minors Protocol Page #:

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

Requested consent process waviers

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Alteration of authorization under HIPPA Privacy Rule No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Consent process shown in an understandable language

Reading level has been estimated No Selection

Comprehension tool is provided No Selection

Short form is provided No Selection

Translation planned or performed No Selection

Certified translation / translator No Selection

Translation and back-translation to/from target language(s) No Selection

Other method No Selection

Clinical Trial

Involves human participants No Selection

Assigned to an intervention No Selection

Evaluate the effect of the intervention No Selection

Evaluation of a health related biomedical or behavioral outcome No Selection

Registerable clinical trial No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus No Selection

Human genetic testing is planned now or in the future No Selection

Involves long-term storage of identifiable biological specimens No Selection

Involves a drug, biologic, or device No Selection

Conducted under an Investigational New Drug exemption or Investigational Device Exemption No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
Missouri Dept of Hlth & Senior Services	FWA00001948	07/28/25	Missouri Dept of Hlth & Senior Services IRB #1	03/10/24	
U.S. Environmental Protection Agency	FWA00012755	06/08/22			

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Aaron Young	04/26/2025	04/29/2025			Co-Investigator		770-488-3745	EXPOSURE INVESTIGATIONS TEAM
Cory Kokko	06/08/2025	05/12/2025			Co-Investigator		913-551-1312	WESTERN SECTION REGION 7
Erin Evans	05/31/2022	05/11/2025			Principal Investigator		913-551-1311	WESTERN SECTION
Karen Scruton	11/01/2024	05/01/2017	11/10/2024		Project Coordinator		770-488-1325	OFFICE OF COMMUNITY HEALTH AND HAZARD ASSESSMENT
Matthew Ferguson	05/05/2023				Co-Investigator		913-551-1310	WESTERN SECTION REGION 7

Dataset yet to be added...

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Davis_Stephanie I. (sgd8) CIO OMB / PRA	06/14/2022	GenIC files for ICRO review and submission to OMB	Paperwork Reduction Act Form	JNCEI OMB 6-14-2022 to ICRO.zip
	Young_Aaron (wrh6) CIO HSC	06/13/2022	Complete OMB submission clean documents	Other	JNCEI OMB 6-13-2022 final.zip
	Young_Aaron (wrh6) CIO HSC	06/13/2022	This file only has new documents and those with revisions	Other	JNC EI OMB 6-13-2022 Revisions with Track Changes.zip
	Davis_Stephanie I. (sgd8) CIO HSC	06/04/2022	GenIC files in zipfile with OS edits and comments to be addressed	Paperwork Reduction Act Form	Files rev OS 20220604.zip
	Young_Aaron (wrh6) CIO HSC	06/01/2022	Complete OMB package	Other	JNC EI OMB 6-1-2022.zip
	Young_Aaron (wrh6) CIO HSC	05/13/2022	Zip file of all attachments combined for Jasper and Newton County EI OMB	Other	Final OMB Jasper and Newton County EI.zip
	Young_Aaron (wrh6) CIO HSC	05/13/2022	This is the Project Determination file with your most recent comment addressed. All changes have been updates in the SGTARS system.	Other	eClearance Project Determination 5-11.docx
	Davis_Stephanie I. (sgd8) CIO HSC	05/11/2022	Zipfile of GenIC files with OS review comments	Paperwork Reduction Act Form	Files rev OS.zip

Current	Young_Aaron (wrh6) Project Contact	05/09/2022	Attachment 2 Supporting Statement B updated	Other	Att2_Jasper and Newton County SupStatement B - 0923-0048_5-9-22.docx
Current	Young_Aaron (wrh6) Project Contact	05/09/2022	Gen IC Submission updated 5-9-22	Other	Jasper and Newton County GenIC Submittal 5-9-22.docx
Current	Young_Aaron (wrh6) Project Contact	05/09/2022	Updated Supporting Statement A 5-9-22	Other	Att1_Jasper and Newton MO EI SupStatement A_5-9-22.docx
	Li_Zheng (kzl4) Office Approver Projects	05/06/2022	SSA with OCHHA/ADS comments /edits.	Paperwork Reduction Act Form	Att1_Jasper and Newton MO EI SupStatement A_ks zl.docx
	Li_Zheng (kzl4) Office Approver Projects	05/06/2022	SSB with OCHHA/ADS comments /edits.	Paperwork Reduction Act Form	Att2_Jasper and Newton County SupStatement B - 0923-0048_ks zl.docx
Current	Young_Aaron (wrh6) Project Contact	05/05/2022	Attachment 1 Supporting Statement A	Other-Supporting Statement A	Att1_Jasper and Newton MO EI SupStatement A_ks .docx
Current	Young_Aaron (wrh6) Project Contact	05/05/2022	Attachment 4: EI participant questionnaire	Data Collection Form	Att4 JNC Questionnaire JNC EI 0923_0048.docx
Current	Young_Aaron (wrh6) Project Contact	05/05/2022	Attachment2: Supporting Statement B	Other-Supporting Statement B	Att2_Jasper and Newton County SupStatement B - 0923-0048_ks.docx
Current	Young_Aaron (wrh6) Project Contact	05/05/2022	Attachment 7 Prior EI Final report	Other-Example of Prior EI Final Report	Att7 EX EI report_Anaconda_Co_Smelter_.pdf
Current	Young_Aaron (wrh6) Project Contact	05/05/2022	Attachment 6: Sample Results Letter (Attachment 5 is the autogenerated research determination form)	Other-Sample Results Letter to Participants	Att6 JNC Sample Results Letters0923-0048.docx
Current	Young_Aaron (wrh6) Project Contact	05/05/2022	Attachment 8: Privacy Impact Assessment Form	Other-Privacy Impact Assessment Form	Att8_PIA_Requests_JNC.pdf
Current	Young_Aaron (wrh6) Project Contact	05/05/2022	Attachment 3B: Adult Consent Form	Consent Form	Att3B_Adult Consent JNC EI 0923-0048.docx
	Young_Aaron				

Current	(wrh6) Project Contact	05/05/2022	Attachment 3C: Parental Permission form	Consent Form	Att3C parental perm JNC E 0923-0048I.docx
Current	Young_Aaron (wrh6) Project Contact	05/05/2022	Attachment 3D: Missouri Department of Health and Senior Services consent form	Consent Form	Att3D MDHSS consent form JNC EI 0923-0048.docx
Current	Young_Aaron (wrh6) Project Contact	05/05/2022	Attachment 9: Protocol for the proposed EI that has been through the eClearance process.	Protocol	Att9 JNC EI Protocol 0923-0048.docx
Current	Young_Aaron (wrh6) Project Contact	05/05/2022	Attachment 3E: Environmental Protection Agency consent form	Consent Form	Att3E EPA consent form JNC EI 0923-0048.docx
Current	Young_Aaron (wrh6) Project Contact	05/05/2022	Generic Information Collection Form	Other-Generic Information Collection Submittal Form	Jasper and Newton County GenIC Submittal 5_3_22.docx
Current	Young_Aaron (wrh6) Project Contact	05/05/2022	Attachment 3: All Privacy and consent forms (3A-3E)	Consent Form	Att3 JNC privacy and consent forms 0923-0048.docx
Current	Young_Aaron (wrh6) Project Contact	05/05/2022	Attachment 3A: Privacy Statement	Consent Form	Att3A JNC privacy stmt 0923-0048.docx



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